

**REMARKS**

With entry of this amendment, claims 16-18, 20, 21, and 28-34 are pending in this application, all of which stand rejected. Withdrawn claims 35-48 have been cancelled. Based on the foregoing amendments and following remarks, reconsideration and allowance of this application is respectfully requested.

**Claim Rejections-35 U.S.C. §102**

Claims 16-18, 20, 21, and 28 stand rejected under 35 U.S.C. §102(b), as being anticipated by U.S. Patent Publication No. 2001/0041821 to Wilk ("Wilk"). Applicant respectfully traverses this rejection, since Wilk does not disclose each and every element required by these claims.

In particular, the cuff 12 of the Wilk device is not crescent-shaped, as illustrated in Fig. 17 of the present application, but rather C-shaped (see paragraph 55 of Wilk). Thus, Applicant submits that independent claim 16, as well as the claims depending therefrom (claims 17, 18, 20, and 28), are not anticipated by Wilk, and as such, respectfully request withdrawal of the §102 rejections of these claims.

**Claim Rejections-35 U.S.C. §103**

**Hess and Cross**

Claims 16 and 21 Claims stand rejected under 35 U.S.C. §103, as being obvious over U.S. Patent No. 4,285,347 issued to Hess ("Hess") in view of U.S. Patent Publication No. 2002/0111661 to Cross et al. ("Cross"). Applicant respectfully traverses this rejection, since neither of Hess nor Cross disclose, teach, or suggest the combination of elements required by these claims.

Applicant cannot determine from the office action whether the Examiner has applied the teachings of Cross to modify the shape of the insulated sheath 24 or to modify the shape of the lateral members 32, 34 of the Hess device. That is, the Examiner cites col. 2, lines 47-64 for the teaching that Hess "discloses a curved, resilient, tubular epidural lead that can be straightened by a force but returns to its curved shape when the force is removed." However, the only structure disclosed in Hess that can be alternately placed between an a straight configuration and a curved configuration is the combination of the lateral members 32, 34, which does not constitute a resilient, hollow tubular membrane structure, and is not a structure with which the electrode 30 is associated, as required by claim 16. The insulating sheath 24 may be a hollow tubular structure, but is not configured to be placed between a collapsed and expanded configuration.

Regardless of this, there is no suggestion in Cross that either of the sheath 24 or lateral members 32, 34 could be modified into a hollow crescent-shaped tubular membrane structure. In particular, modification of the sheath 24 into a crescent-shaped would appear to serve no particular purpose or have any advantage that would motivate one of ordinary skill in the art to make such a modification. And there is simply no suggestion to somehow transform the lateral members 32, 34 into a resilient tubular membrane structure. Significantly, the lead paddle 14 illustrated and described in Cross is not crescent-shaped, and thus, there can be no teaching in Cross to make anything crescent-shaped. Cross merely teaches that the cross-section of a two-dimensional lead paddle 14 can be curved to match the curvature of the dura mater (see paragraph [0029] of Cross). One of ordinary skill in the art would simply not be motivated to modify the Hess device, such that it includes a three-dimensional structure in the form of a hollow, tubular membrane structure

that can be expanded into a crescent cross-sectional shape, based on the mere teaching that a two-dimensional paddle can be curved.

Thus, Applicant submits that claims 16 and 21 are not obvious over the combination of Hess and Cross, and as such, respectfully request withdrawal of the §103 rejections of these claims.

Wilk

Claims 21, 29, and 30 stands rejected under 35 U.S.C. §103, as being obvious over Wilk in view of U.S. Patent No. 4,141,365 issued to Fischell et al. ("Fischell"). Applicant respectfully traverses this rejection, since neither Wilk nor Fischell, alone or in combination, discloses, teaches, or suggests the combination of elements required by these claims.

With respect to claim 21, the Examiner has stated that "it would have been obvious to . . . modify the invention of Wilk to be made to fit snugly around/in epidural space since the lead is of size and shape to fit around a heart it is of similar size to be 'snugly' fit in epidural space." Applicant disagrees. In particular, the circumference around the heart is much bigger than the cross-section of an epidural space, and therefore, the Wilk device would not be able to fit within an epidural space—at least not in its expanded configuration to allow any electrodes associated with it to be placed against the dura mater.

In addition, the entire purpose of the Wilk device is disclosed as assisting cardiac function—not stimulation of the spinal cord (see Abstract, background of the invention, and summary of the invention). To transform the Wilk device into a spinal cord stimulation device would clearly defeat this purpose, and thus, there can be no suggestion to make such a modification. It is an established principle that if a proposed modification would

render the prior art device or method being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. (See M.P.E.P. §2143.01). See In re Gordon, 733 F.2d 900 (Fed. Cir. 1984).

With respect to claims 29 and 30, Wilk does not disclose, teach, or suggest the use of a resilient, hollow tubular membrane structure having a crescent-shaped cross-section when expanded, as required by independent claim 16 from which claims 29 and 30 depend, and Fischell does not supplement this failed teaching.

Thus, Applicant submits that claims 16, 29, and 30 are not obvious over the combination of Wilk and Fischell, and as such, respectfully request withdrawal of the §103 rejections of these claims.

#### Conclusion

Based on the foregoing, it is believed that all claims are allowable, and thus, a Notice of Allowance is respectfully requested. If the Examiner has any questions or comments regarding this amendment, the Examiner is respectfully requested to contact the undersigned at (949) 724-1849.

Respectfully submitted,

**VISTA IP LAW GROUP LLP**

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By: 

Michael J. Bolan  
Reg. No. 42,339

Customer No. 41696  
Vista IP Law Group LLP  
12930 Saratoga Avenue, Suite D-2  
Saratoga, CA 95070